Ministry of Health, Welfare and Sport

Specification Sheet

Product:	**Cannabis flos, variety Bedrolite** (hemp flowers)
	CBD-dominant type
Market:	to be prescribed to patients as a medicinal product.
Strength:	tetrahydrocannabinol: ≤ 1.0% cannabidiol: ≥ 5.0%
Dosage form:	flowers, granulated
Package size:	5 grams in containers, 400 grams in bags
Analytical Monograph:	European Pharmacopoeia (Ph. Eur.) 07/2024:3028

	Method	**Specification**
Odour	Ph. Eur. (current ed.) 2.3.4	Characteristic for Cannabis flower
Appearance	Visual	Dried, fragmented, fully developed female inflorescence of Cannabis sativa L. Stalks are no longer than 2.0 cm and only 20% of the stalks are between 1.5 and 2.0 cm.
Identification		
Macroscopic botanical characters	Monograph	Conform Identification A.
Microscopic botanical characters	Monograph	Conform Identification B.
High-performance thin-layer chromatography	Monograph	Comparable with reference and test solutions CBD-dominant type. Conform Identification C.
Loss on drying	Monograph	≤ 12.0%
Foreign material	Monograph	Maximum 2 per cent. It does not contain any seeds or other foreign elements and the whole herbal drug does not contain any leaves more than 1.0 cm in length.

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The Office of Medicinal Cannabis (OMC) is part of the CIBG agency of the Ministry of Health, Welfare and Sport

Internet address:
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	Method	**Specification**	
Aflatoxins	Ph. Eur. 2.8.18 (current ed.)	Aflatoxin B1	≤ 2 µg/kg
		Sum of aflatoxins B1, B2, G1 and G2	≤ 4 µg/kg
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.8.13	
Heavy metals	Monograph	Arsenic	≤ 0.2 ppm
		Cadmium	≤ 0.3 ppm
		Lead	≤ 0.5 ppm
		Mercury	≤ 0.1 ppm
Assay	Monograph	Tetrahydrocannabinol (THC, total eq.)	≤ 1.0%
		Cannabidiol (CBD, total eq.)	≥ 5.0%
Related substances	Monograph	Cannabinol (CBN, total eq.)	≤ 1.0%
Microbial contamination	Ph. Eur. (current ed.) 2.6.12, 2.6.13	Total aerobic microbial count (TAMC)	≤ 10^2 CFU/gram
		Total combined yeasts/moulds count (TYMC)	≤ 10^1 CFU/gram
		Staphylococcus aureus	Absent (1 gram)
		Pseudomonas aeruginosa	Absent (1 gram)
		Bile-tolerant gram-negative bacteria	Absent (1 gram)

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